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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/035,914 | 11/07/2001 | David E. Weinstein | 96700/677 | 2216 |

7590 02/25/2003

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EXAMINER

JOHANNSEN, DIANA B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1634

DATE MAILED: 02/25/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,914

Applicant(s)

WEINSTEIN, DAVID E.

Examiner

Diana B. Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 31-64 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

ELECTION/RESTRICTION

1. This application has been transferred from Examiner Liping Chen in Art Unit 1632 to Examiner Diana Johannsen in Art Unit 1634.
2. Applicant's election with traverse of Group IX with respect to Group X in Paper No. 8 is acknowledged. However, in paper no. 8, Applicant canceled claims 1-30, amended claims 31-34, and added new claims 35-64. In view of applicant's amendments and arguments of paper no. 8, the Election/Restriction requirement of paper no. 7 is withdrawn, and restriction of pending claims 31-64 is required as set forth below.
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 31-43, 49-56, and 62-64, drawn to diagnostic methods requiring detection of polypeptides, classified in, at least, for example, class 435, subclass 7.1.
 - II. Claims 31-36, 44-50, 52, and 57-63, drawn to diagnostic methods requiring detection of nucleic acids, classified in, at least, for example, class 435, subclass 6.
4. It is noted that applicants have presented several claims in improper Markush format (see *Ex parte Markush*, 1925 C.D. 126 and *In re Weber*, 198 USPQ 328). In claims 31-36, 49-50, 52, and 62-63, methods of detecting nucleic acids and polypeptides are improperly joined. Nucleic acids and polypeptides differ in structure and function to such an extent that they are considered separately patentable. Further, the steps and reagents required to detect nucleic acids differ from the steps and

reagents required to detect polypeptides. Accordingly, claims 31-36, 49-50, 52, and 62-63 have been included in both Group I and Group II, and will be examined only to the extent those claims read on the elected group.

Upon election, to avoid rejection of the claims as being in improper Markush format, applicants are also required to amend the claims to set forth the elected inventive group.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct methods. Invention I is drawn to methods in which polypeptides are detected, while Invention II is drawn to methods in which nucleic acids are detected. Inventions I and II require the detection of molecules that are structurally and functionally distinct from one another: polypeptides are composed of amino acids linked by peptide bonds and function in, e.g., enzymatic and/or immunological assays, while polynucleotides are composed of nucleotides linked by phosphodiester bonds and function in, e.g., methods of nucleic acid hybridization and/or amplification. Further, Invention I and II require a practitioner to employ different types of reagents in unrelated method steps: for example, Invention I requires the use of antibodies in steps of binding and detecting polypeptides, while Invention II requires the use of, e.g., nucleic acid probes and primers in steps of nucleic acid hybridization and amplification. Accordingly, Invention I and II are patentably distinct from one another.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and

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recognized divergent subject matter, and because Inventions I-II require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner, and therefore restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", with a long horizontal flourish extending to the right.

Diana B. Johannsen
February 21, 2003